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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/393,023	09/09/99	MEISSNER	P PF-200

KM

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EXAMINER	
KAUFMAN,C	
ART UNIT	**PAPER NUMBER**
1646	8

DATE MAILED: 12/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/393,023	MEISSNER ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to polynucleotide, vector, host cell, method of producing modified cell, method of producing polypeptide, polypeptide, and agonist, classified in Class 435, subclasses 69.1.

II. Claim 14 and 15, drawn to antagonist and antibody, classified in Class 530, subclass 388.24.

III. Claims 16-18, drawn to process for identifying agonist or antagonist with binding assay, classified in Class 435, subclass 7.21.

IV. Claim 19, drawn to method of diagnosing by mutation analysis, classified in Class 435, subclass 6.

V. Claim 20, drawn to method of detecting polypeptide presence, classified in Class 435, subclass 7.1, for example (classification dependent on method steps).

The inventions are distinct, each from the other because of the following reasons:

The protein of Group I is related to the antibody of Group II by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because the protein can be used for another and materially different process other than for production of the antibody, such as to assay or purify the natural receptor for the protein or in assays for the identification of agonist or antagonists of the receptor protein. The methods of Group I are unrelated to the antibody of Group II because the antibody is not required for the methods and can be used in a materially different process such as immunoprecipitation. The nucleic acid encodes the protein, but cannot itself be used to make the antibody or antagonist. The protein is related to the antagonist because they interact, however, they are necessarily structurally and functionally distinct.

Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein of Group I which is required for the assays of Group III can be used for a materially different process such as in performing as an antigen in the making of an antibody or in isolation of its native receptor. Additionally, the methods of Group I are distinct from those of Group III because they have materially different steps and purposes/endpoints. The nucleic acid cannot be used in the methods of Group III.

The nucleic acid of Group I and method of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acid of Group I can be used for a materially different process such as for screening a cDNA library to isolate species homologues or to produce the encoded protein. The methods of Groups I and IV are distinct because they are unrelated in process steps and function/use.

The products of Group I are unrelated to the method of Group V in that the agonist or nucleic acid of Group I is not required for the detection of the protein in a sample from a host. This process maybe practiced with antibodies to the protein. Additionally, the agonist or nucleic acid may be used for materially different processes such as agonist activation of the receptor or nucleic acid blotting (*e.g.*, Southern blotting). The methods of Groups I and V are distinct because the methods of Group I do not require components that can be used in that of Group V (e.g. antibodies or sample from host). They also have materially different process steps.

Group II is unrelated to and distinct from Groups III and IV. The antibody of Group II is not required for the processes of Groups III and IV. Additionally the antibody may be used for materially different processes such as for immunoaffinity purification of its antigen or for immunocytochemistry to identify protein presence in specific tissues.

The products of Groups II and processes of Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibody of Group II may be

used for another materially different process such as to purify the polypeptide. Additionally, the process of Group V can be practiced with another materially different product, such as with its native receptor.

Groups III-V are unrelated processes that are functionally distinct and may be practiced in different manners, and if determined to be patentable, would also be patentably distinct with one not required for the other. The process for identifying agonists and antagonist of Group III does not require either DNA or antibodies, but does require the CGF receptor. The method of Group IV for diagnosing through mutation analysis requires polynucleotides but not antibodies or the receptor. The method of Group V of detecting polypeptide presence from a cell sample can be practiced with the antibody but not DNA, nor does it require that the receptor be present.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one group is not coextensive with any other, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

December 12, 2000